Preparing for an FDA or Sponsor Inspection

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Upon notification of an FDA inspection, please contact the Office of Regulatory Affairs immediately for guidance and assistance. The ORA provides one-on-one inspection/audit preparation guidance, education on how to interact with the FDA, and provides support for responding to the FDA's findings, if needed.

If there is a concern about the study preparedness for a Sponsor audit, contact the Office of Regulatory Affairs to request an audit readiness assessment for both industry and investigator-initiated studies. This program helps ensure compliance with FDA, GCP, and IRB regulations, and UCLA Health System policies and guidance, as related to clinical research. The results of the pre-audit assessment will be provided for investigators and teams.

Visit FDA Inspections & Alerts to learn more.

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